Scilex Holding Company Announces Final Court Approval of a Settlement Agreement with Takeda Pharmaceuticals to Resolve the Paragraph IV Patent Infringement Lawsuit Relating to Scilex's intent to Expand the Label for its FDA-Approved Liquid Colchicine Product, Gloperba®

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PALO ALTO, Calif., May 14, 2024 (GLOBE NEWSWIRE) -- Scilex Holding Company (Nasdaq: SCLX, "Scilex" or "Company"), an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain, today announced that the 45-day review period for the U.S. Federal Trade Commission and U.S. Department of Justice to comment on or object to the Settlement Agreement (the "Settlement Agreement") entered into by the Company and its wholly owned subsidiary, Scilex Pharmaceuticals Inc. ("Scilex Pharma" and, together with the Company, the "Scilex Parties") with Takeda Pharmaceuticals U.S.A., Inc. and Takeda Pharmaceuticals Company LTD. (collectively "Takeda") to resolve the Paragraph IV patent infringement lawsuit (the "Action") that Takeda filed against the Scilex Parties in the federal district court in Delaware in November 2023 has expired and the U.S. District Court for the District of Delaware entered a Consent Judgment on May 3, 2024, approving the Settlement Agreement. The Action arose from Scilex's filing of a revised label with the FDA seeking to expand the label for its FDA-approved liquid colchicine product, Gloperba®, a preventive treatment for gout. As part of the Settlement Agreement, the Scilex Parties entered into a License Agreement with Takeda granting the Company and its affiliates a non-exclusive license to certain patents owned by Takeda. The terms of those agreements are confidential.

Based on that resolution of those ANDA patent issues, Scilex Pharma has now submitted a copy of that Consent Judgment to the FDA and requested that the FDA convert its tentative approval of Scilex Pharma's proposed label expansion for Gloperba ® into a final approval of the expanded Gloperba® label. With the resolution of this patent issue, Scilex Pharma believes that it has satisfied all requirements for final FDA approval of the expanded Gloperba® label.

The expansion of Gloperba® label would provide the Company with the ability to utilize dosing flexibility of liquid formulation to address unmet medical needs and provide specific dosing guidance to patients with renal impairment as set out below:

- Patients with mild or moderate renal or hepatic impairment should be considered for dose adjustment.
- For patients with severe renal impairment, the starting dose should be 0.3 mg/day.
- For patients undergoing dialysis, the total recommended dose should be 0.3 mg and be given twice a week.

A recent market research study conducted by the Company among rheumatologists revealed a high degree of interest in Gloperba® as a liquid colchicine formulation designed for precision dosing.[1] Specifically, clinicians using colchicine for prophylaxis of gout flares in adults indicated a strong likelihood to use Gloperba® instead of tablets/capsules in certain at-risk patient populations who have a clinical need for lowered precision dosing to mitigate the risk of colchicine toxicity. Notably, the American College of Rheumatology (ACR) guidelines also reflect this need.[2]

"Colchicine in a form that allows incremental dose adjustment would not only more easily permit patient adherence with the American College of Rheumatology (ACR) Guideline for the Management of Gout, but also allow personalized adjustment for patients who do not tolerate their defined dose or might benefit from incremental adjustments of dose up or down," said Michael Pillinger, MD, NYU Langone Health, New York, NY.

For more information on Scilex Holding Company, refer to www.scilexholding.com

For more information on Gloperba®, including Full Prescribing Information, refer to www.gloperba.com.

For more information on ELYXYB®, including Full Prescribing Information, refer to www.elyxyb.com.

For more information on ZTlido® including Full Prescribing Information, refer to www.ztlido.com.

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About Scilex Holding Company

Scilex Holding Company is an innovative revenue-generating company focused on acquiring, developing and commercializing non-opioid pain management products for the treatment of acute and chronic pain. Scilex targets indications with high unmet needs and large market opportunities with non-opioid therapies for the treatment of patients with acute and chronic pain and are dedicated to advancing and improving patient outcomes. Scilex's commercial products include: (i) ZTlido ® (lidocaine topical system) 1.8%, a prescription lidocaine topical product approved by the U.S. Food

and Drug Administration (the “FDA”) for the relief of neuropathic pain associated with postherpetic neuralgia, which is a form of post-shingles nerve pain; (ii) ELYXYB®, a potential first-line treatment and the only FDA-approved, ready-to-use oral solution for the acute treatment of migraine, with or without aura, in adults; and (iii) Gloperba® , the first and only liquid oral version of the anti-gout medicine colchicine indicated for the prophylaxis of painful gout flares in adults, expected to launch in the first half of 2024.

In addition, Scilex has three product candidates: (i) SP-102 (10 mg, dexamethasone sodium phosphate viscous gel) (“SEMDEXA™” or “SP-102”), a novel, viscous gel formulation of a widely used corticosteroid for epidural injections to treat lumbosacral radicular pain, or sciatica for which Scilex has completed a Phase 3 study and has granted Fast Track status from the FDA in 2017; (ii) SP-103 (lidocaine topical system) 5.4%, (“SP-103”), a next-generation, triple-strength formulation of ZTlido, for the treatment of chronic neck pain and for which Scilex has recently completed a Phase 2 trial in low back pain. SP-103 has been granted Fast Track status by the FDA in low back pain ; and (iii) SP-104 (4.5 mg, low-dose naltrexone hydrochloride delayed-release capsules) (“SP-104”), a novel low-dose delayed-release naltrexone hydrochloride being developed for the treatment of fibromyalgia, for which Phase 1 trials were completed in the second quarter of 2022.

Scilex Holding Company is headquartered in Palo Alto, California.

Forward-Looking Statements

This press release and any statements made for and during any presentation or meeting concerning the matters discussed in this press release contain forward-looking statements related to Scilex and its subsidiaries under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements regarding whether the FDA chooses to convert its tentative approval of Scilex Pharma’s proposed label expansion for Gloperba® into a final approval, Scilex’s belief that it has satisfied all requirements for final FDA approval of the expanded Gloperba® label, the potential of Gloperba® label’s expansion to provide Scilex with the ability to utilize dosing flexibility, estimates for potential demand for Gloperba®, the belief that Scilex is well-positioned to market and distribute Gloperba®, Scilex’s expectation to launch Gloperba ® in the first half of 2024 , each parties’ releases of claims arising from the captioned patent infringement lawsuit, the granting of the non-exclusive license and FDA’s approval for the modification of the Gloperba ® label.

Risks and uncertainties that could cause Scilex’s actual results to differ materially and adversely from those expressed in our forward-looking statements, include, but are not limited to: risks associated with the unpredictability of trading markets and whether a market will be established for Scilex’s common stock; general economic, political and business conditions; risks related to COVID-19 (and other similar disruptions); the risk that the potential product candidates that Scilex develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all; risks relating to uncertainty regarding the regulatory pathway for Scilex’s product candidates; the risk that Scilex will be unable to successfully market or gain market acceptance of its product candidates; the risk that Scilex’s product candidates may not be beneficial to patients or successfully commercialized; the risk that Scilex has overestimated the size of the target patient population, their willingness to try new therapies and the willingness of physicians to prescribe these therapies; risks that the outcome of the trials and studies for SP-102, SP-103 or SP-104 may not be successful or reflect positive outcomes; risks that the prior results of the clinical and investigator-initiated trials of SP-102 (SEMDEXA™), SP-103 or SP-104 may not be replicated; regulatory and intellectual property risks; and other risks and uncertainties indicated from time to time and other risks described in Scilex’s most recent periodic reports filed with the Securities and Exchange Commission, including Scilex’s Annual Report on Form 10-K for the year ended December 31, 2023 and any subsequent Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, including the risk factors set forth in those filings. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and Scilex undertakes no obligation to update any forward-looking statement in this press release except as may be required by law.

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Reference:

1) Scilex market research study of US rheumatologists, Nov-Dec 2023

2) Khanna D, et al. 2012 American College of Rheumatology Guidelines for Management of Gout. Part 2: Therapy and Anti-inflammatory Prophylaxis of Acute Gouty Arthritis. Arthritis Care & Research. Vol. 64, No. 10, October 2012, pp 1447–1461

SEMDEXA™ (SP-102) is a trademark owned by Semnur Pharmaceuticals, Inc., a wholly-owned subsidiary of Scilex Holding Company. A proprietary name review by the FDA is planned.

ZTlido® is a registered trademark owned by Scilex Pharmaceuticals Inc., a wholly-owned subsidiary of Scilex Holding Company.

Gloperba® is the subject of an exclusive, transferable license to use the registered trademark by Scilex Holding Company.

ELYXYB® is a registered trademark owned by Scilex Holding Company.

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